Rulemaking1CEm Resource

From: RulemakingComments Resource
Sent: Monday, September 14, 2015 4:48 PM
To: Rulemaking1CEm Resource
Subject: Comment on PRM-20-28, PRM-20-29, and PRM-20-30
Attachments: NRC-2015-0057-DRAFT-0258.pdf

DOCKETED BY USNRC—OFFICE OF THE SECRETARY

SECY-067
PR#: PRM-20-28, PRM-20-29, and PR-20-30
FRN#: 80FR35870
NRC DOCKET#: NRC-2015-0057
SECY DOCKET DATE: 9/4/15
TITLE: Linear No-Threshold Model and Standards for Protection Against Radiation
COMMENT#: 257

Hearing Identifier: Secy_RuleMaking_comments_Public
Email Number: 1045

Mail Envelope Properties (f3c832ab1621456b940e69e7ffe02ff8)

Subject: Comment on PRM-20-28, PRM-20-29, and PRM-20-30
Sent Date: 9/14/2015 4:47:41 PM
Received Date: 9/14/2015 4:47:42 PM
From: RulemakingComments Resource

Created By: RulemakingComments.Resource@nrc.gov

Recipients:
"Rulemaking1CEm Resource" <Rulemaking1CEm.Resource@nrc.gov>
Tracking Status: None

Post Office: HQPWMSMRS05.nrc.gov

Files	**Size**	**Date & Time**
MESSAGE	295	9/14/2015 4:47:42 PM
NRC-2015-0057-DRAFT-0258.pdf	432580	

Options
Priority: Standard
Return Notification: No
Reply Requested: No
Sensitivity: Normal
Expiration Date:
Recipients Received:

PUBLIC SUBMISSION

As of: 9/5/15 10:08 AM
Received: September 04, 2015
Status: Pending_Post
Tracking No. 1jz-8kxw-t0eq
Comments Due: November 19, 2015
Submission Type: Web

Docket: NRC-2015-0057
Linear No-Threshold Model and Standards for Protection Against Radiation

Comment On: NRC-2015-0057-0086
Linear No-Threshold Model and Standards for Protection Against Radiation; Extension of Comment Period

Document: NRC-2015-0057-DRAFT-0258
Comment on FR Doc # 2015-20722

Submitter Information

Name: steven brown

General Comment

See attached file(s)

Attachments

LNT Petition for Rulemaking_Comments by SBROWN_4SEPT2015

SHB INC., 7505 S. XANTHIA PLACE, CENTENNIAL, COLORADO 80112

Steven H Brown, Certified Health Physicist
303 941 1506; shb12@msn.com

September 4, 2015

Subject: Comments Regarding Petition for Rulemaking; Linear No-Threshold Model and Standards for Protection Against Radiation; Docket ID NRC-2015-0057

Attention: Solomon Sahle, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission

Mr. Sahle:

I wish to thank the U.S. Nuclear Regulatory Commission for the opportunity to provide these comments in response to your Federal Register Notice of Tuesday, June 23, 2015 on this subject.

My name is Steven H. Brown. I have been a practicing health physicist for over 40 years, and have been certified by the American Board of Health Physics since 1983. Throughout much of my professional career, I have worked for licensees of the USNRC and/or Agreement States, primarily in the nuclear fuel cycle, and have been the designated Radiation Safety Officer (RSO) under a number of radioactive material licenses including for uranium recovery, radiochemical laboratories and licenses of broad scope. The comments and opinions expressed herein are exclusively my own.

In general, I am supportive of the three petitioners' recommendations that NRC amend 10 CFR 20 based on newer science that contradicts the LNT ("Linear No-Threshold") hypothesis, given the very large volume of scientific evidence reported in the professional literature over the last 50+ years demonstrating there appear to be existing dose thresholds associated with low levels of ionizing radiation exposure, below which human health effects are either non existence or too low to observe or measure.

The purpose of my brief comments here are not to reiterate or duplicate the arguments and references used by the petitioners' or other commenters (e.g., those of the Wyoming Mining Association and Nancy Standler, MD, Phd which I have read and with which I also agree in principle), particularly as related to evidence of the potential "beneficial" aspects of low level radiation exposure (hormesis). I concur with the implications as have been well articulated by others that this body of evidence indicates at low doses and dose rates the LNT model is suspect and has created a radiophobia that can lead to potentially dangerous decisions (from a public health perspective) by regulators and others with responsibility for public health and safety as a direct result from a "religious" adherence to the LNT model and its implications ("no safe level of radiation exposure", "any dose above zero can cause cancer", etc.).

Rather, my remarks below are intended to address four specific areas that I believe are related to some fundamental aspects of this petition for rulemaking:

- Published positions of the National Health Physics Society related to radiation risk in general, and the potential existence of a "dose threshold", greater than zero, below which there are either no health effects or such effects are to small to be observable or measureable.

- More recent data in the literature[1] demonstrating that the extremely high doses and dose rates associated with the circumstances of the Japanese atomic bomb survivors, upon which the LNT model is almost exclusively based[2], may not be relevant to the low dose rates and low "chronic" exposure conditions of occupational and public exposure scenarios of common experience since and today.

- Use of the concept of "collective dose" to estimate population risk associated with low levels of radiation exposure is "flawed" and can lead to erroneous and potentially "dangerous" public health decisions.

- The ALARA concept ("As Low as Reasonably Achievable"), although useful as a fundamental principle of the radiation protection profession for years and continues to be, has been misunderstood and misapplied in regulatory contexts.

1. Some stated positions of the National Health Physics Society (US) related to radiation risk in general, and the specific potential existence of a "dose threshold".

A. About the Health Physics Society (HPS)

The Health Physics Society, formed in 1956, is a scientific organization of professionals who specialize in radiation safety. Its mission is to support its members in the practice of their profession and to promote excellence in the science and practice of radiation safety. Today, its nearly 6,000 members represent all scientific and technical areas related to radiation safety including academia, government, medicine, research and development, analytical services, consulting, and industry in all 50 states and the District of Columbia. The Society is chartered in the United States as an independent nonprofit scientific organization and, as such, is not affiliated with any government or industrial organization or private entity.

The Society's mission is excellence in the science and practice of radiation safety. Society activities include encouraging research in radiation science, developing standards, and disseminating radiation safety information for the purpose of understanding, evaluating, and controlling the potential risks from radiation relative to the benefits.

[1] More recent than 1956, when the LNT was recommended to be used by the U.S. National Academy of Sciences Committee on Biological Effects of Atomic Radiation (BEAR I)/Genetics Panel

[2] For example, the most commonly referenced study is the Life Span Study of the Radiation Effects Research Foundation (RERF)

B. Excerpts from Position Statements of the Society relevant to Risks of Ionizing Radiation – Potential Existence of Thresholds

Position statements of the HPS are prepared by or under the direction of the Scientific and Public Issues Committee and approved by the Board of Directors in accordance with the Bylaws and Rules of the Society. Position statements are prepared after an official position has been approved by the Board of Directors. They are the positions that the HPS takes on a topic and are concise declarations regarding an issue relevant to radiation safety. Examples of official HPS position statements relevant to this discussion are discussed below. These can be accessed at the HPS website.
Go to http://hps.org/hpspublications/positionstatements.html.

From HPS Position Statement PS010-2: "Radiation Risks in Perspective"
(Adopted: January 1996; Revised: July 2010)

There is substantial and convincing scientific evidence for health risks following high-dose exposures. However, below 5–10 rem (which includes occupational and environmental exposures), risks of health effects are either too small to be observed or are nonexistent….

Radiogenic health effects (primarily cancer) have been demonstrated in humans through epidemiological studies only at doses exceeding 50–100 mSv (Ed. Note 5 – 10 Rem) *delivered at high dose rates. Below this dose, estimation of adverse health effect remains speculative. Risk estimates that are used to predict health effects in exposed individuals or populations are based on epidemiological studies of well-defined populations (for example, the Japanese survivors of the atomic bombings in 1945 and medical patients) exposed to relatively high doses delivered at high dose rates. Epidemiological studies have not demonstrated adverse health effects in individuals exposed to small doses (less than 100 mSv) delivered in a period of many years.*

From HPS Position Statement PS013-1: *"*Occupational Radiation Safety Standards and Regulations Are Sound" (Adopted: March 2000; Revised: July 2012)

The most reliable studies of the effects of radiation exposure at the low levels received by occupational workers have not been able to detect adverse health effects associated with lifetime exposures smaller than approximately 0.1 Sv. (Ed note: 10 Rem)

Summary and Implications:

These official positions of the Health Physics Society suggest that there may be a dose threshold, perhaps at about 100 mSv (10 Rem) exposure, below which risks of health effects are either too small to be observed or are nonexistent. Accordingly, one could conclude from this that extrapolating risks of high doses and dose rates through to zero (as in the case of LNT) may not be valid.

2. The extremely high doses and dose rates associated with the circumstances of the Japanese atomic bomb survivors may not be relevant to establishing radiological risk at very low doses and dose rates.

As discussed by the petitioners and alluded to here, the current recommendations and regulations regarding control of radiation exposure are based on calculating cancer risk as a function of cumulative dose using a linear no-threshold cancer risk model (LNT) based on the acute high dose rate exposures received by the Japanese atomic bomb survivors. The underlying assumption in regulation is that risk of radiation-induced cancer is proportional to cumulative dose without threshold. In conflict with this position are the studies of protracted exposures from internally-deposited radionuclides in people and laboratory animals that have demonstrated that cancer induction risk is a function of average dose rate for protracted exposures to ionizing radiation. At lower average dose rates, cancer latency can exceed natural lifespan leading to a virtual threshold.

These studies, published in the professional literature over many years are numerous, and to summarize them here would be laborious. Additionally, and most importantly, I am not a radiation biologist nor epidemiologist and proper treatment of the details of this subject are beyond my expertise. However, below are the conclusions presented directly from a recent publication on this subject (Raabe 2011). Many of the references provided by Dr. Raabe at the end of his paper provide supportive and substantive evidence for his premise and conclusions (e.g., see also Evans 1943, 1974; Book S A et al 1980, Rosenblatt L S et al1990; Raabe 2010; see also Brenner and Raabe 2001):

- Cancer *induction* risk associated with protracted or fractionated ionizing radiation exposure is a non-linear function of *lifetime average dose rate to the affected tissues* and exhibits a virtual threshold at low lifetime average dose rates;

- Cumulative radiation dose is neither an accurate nor an appropriate measure of cancer *induction* risk for protracted or fractionated ionizing radiation exposure except for describing the virtual threshold for various exposures; and

- Cancer *promotion* risk for ongoing lifetime biological processes is a relative process as seen in the RERF studies of the Japanese atomic bomb survivors for brief high dose-rate exposures to ionizing radiation. It cannot be used to estimate cancer *induction* risk from protracted or fractionated ionizing radiation exposures over long times and at low dose rates.

Summary and Implication:

These perspectives suggest that the fundamental epidemiological and dosimetric basis from which the LNT model is derived is not valid for the low dose rates and low “chronic” exposure conditions of occupational and public exposure scenarios of common experience today. This is because, based on these studies, it is the lifetime average dose rate, not the cumulative dose that determines the cancer risk such that a virtual threshold at low lifetime average dose rates appears to exist.

3. Use of the concept of "collective dose" to estimate population risk / detriment associated with low levels of radiation exposure can lead to erroneous and potentially "dangerous" public health decisions.

The concept of "collective dose" has been a common practice by US regulators to estimate the total risk or health detriment to a population from a nuclear activity, project or facility. This is typically done by summing the total doses projected to a regional population (typically expressed as "person rem") and then multiplying this population dose by a regulator approved cancer related risk factor (e.g., 5.7 x 10^{-4} cancers per person-rem; ICRP 2007).

Although the maximum or average doses to any single member of the public are almost always quite small in these analysis (typically small fractions of the NRC public exposure limit from licensed facilities, i.e., 1 mSv / year – 10 CFR 20.1301) and even smaller fractions of the natural background across the US (e.g., 3 – 6 mSv / year; NCRP 2009), nonetheless in highly populated areas, large numbers of person rem can be calculated.

For example:

In an affected population of 1 million people within an 80 km (50 miles) radius of the nuclear facility, who receive individual exposures from licensed activities above background of 10 mrem / year results in a "collective dose" of 10^4 person rem. Multiplying by the carcinogenic risk factor of 5.7 X 10^{-4} cancers per person rem results in a public health detriment of 5.7 cancers / year. That is, the implication from this analysis is 5-6 people per year "will die" from this nuclear activity. Needless to say, these analyses almost never consider the comparison of using this method to predict the annual cancer incidence resultant from this populations' natural background radiation exposure. In my example here, this would be 0.3 – 0.6 rem / year X 10^6 persons X 5.7 X 10^{-4} cancers/person rem = 170 – 340 deaths / year!

An example I would offer to demonstrate the fallacy of the collective dose concept is the "aspirin scenario". Assume there are 100 people in the room and each one takes an aspirin. The collective dose is 100 "person aspirin" and there would be no expectation of any health related detriment or effect to this population as a result. If however only one of the 100 people in the room took all 100 aspirin, the collective dose would also be 100 "person aspirin" but in this case, there would probably be serious health related detriment to this person without near term medical intervention. That is, a 10 mrem exposure to any individual is not expected to result in a health detriment, no matter how many people receive the 10 mrem exposure.

Summary and Implications:

As demonstrated above, use of the collective dose concept in some situations can produce "absurd" results. This can subsequently lead to incorrect and potentially "irresponsible" conclusions by decision makers regarding prioritization of energy related resources and activities. These circumstances can have significant impacts on access to affordable energy by our and future generations of Americans with significant implications for our national security.

Additionally, and as should be obvious and of equal or greater importance, use of such "absurd" results during public emergencies to establish the appropriate emergency response can lead to very serious consequences in the interest of public safety and health.

4. The ALARA concept ("As Low as Reasonably Achievable") has been misunderstood and misapplied in regulatory contexts.

Two of the petitioners, PRM-20-28 and PRM-20-29, recommended that the ALARA concept be removed from the regulations, for reasons related to perpetuation of radiophobia and/or it requires reduction of radiation doses that are harmless and may be hermetic.

ALARA has been a fundamental element and principle of US and international systems of dose limitation for decades (ICRP 1977, ICRP 2007). Sometimes linked with and related to the principle of "optimization" (quantification and balance between risks and benefits; e.g., see ICRP 1983), its basic tenants and inherent assumptions have been that since there is some uncertainty regards to risks to humans associated with radiation exposure and the ability to quantify the resultant benefits achieved from the nuclear related activity that produces the exposure, it is both prudent and responsible to maintain exposures as low as is *reasonably* achievable (emphasis added). Application of ALARA considerations has been ubiquitous in decision making related to the design and operations of nuclear facilities and almost "second nature" with radiation protection professionals and facility staffs. Particularly regarding occupational exposure settings, radiation protection and operations staffs inherently ask the question " is there a practical / reasonable way to better design the system or do the job that can reduce exposure further, while maintaining the benefit to be derived from the activity". In my opinion, this is sensible and responsible and an important part of what a health physicist's job is and what we do.

However, the "problem" has been that the meaning and purpose of ALARA has been misunderstood and misapplied, particularly in the regulatory context as related to attempts to reduce already very small exposures of workers and the public. Lets begin with "first principles" – the definition itself.

From USNRC NRC 10 CFR 20.1003, *Standards for Protection Against Radiation, Definitions* **(emphasis by me***)*

ALARA (acronym for "as low as is reasonably achievable") means making every ***reasonable*** *effort to maintain exposures to radiation as far below the dose limits in this part as is* ***practical*** *consistent with the purpose for which the licensed activity is undertaken, taking into account the* ***state of technology****, the* ***economics*** *of improvements in relation to state of technology, the* ***economics*** *of improvements in relation to benefits to the public health and safety, and other* ***societal*** *and* ***socioeconomic considerations****, and in relation to utilization of nuclear energy and licensed materials in the public interest.*

The purpose of my points of emphasis in NRC's definition above is to point out the obvious. ALARA never was intended to mean "as low as you can go". The ALARA principle should not be misinterpreted as simply a requirement for dose reductions irrespective of the dose level; sound judgment with considerations of reasonableness, practicality and economics are essential in its proper application. Procedures and documentation required to implement the

ALARA principle can and should be less formally applied, as the annual dose to an individual is reduced farther and farther below the applicable occupational exposure limits. If the estimated (or actual as measured via dosimetry) doses are already small fractions of the applicable limit (e.g., < 20 - 30 %), regulatory action to require the licensees to "demonstrate or prove doses are ALARA" should not be necessary, and in fact, may be counterproductive.

Regarding public exposure, the same considerations should apply. If the current facility design and circumstances result in projected (or measured and calculated via combinations of effluent sampling, environmental monitoring, dispersion modeling, etc.) are already a small fraction of the 10CFR20.1301 exposure limit of 1 mSv / year, there should be no need to regulate to "prove" it is ALARA. This circumstance is particularly relevant for licensed uranium recovery facilities in the western US, where the public's potential exposure from licensed activities and materials is by and large from the same radionuclides as their natural background exposure (which in some mineralized locations can be upwards of 6– 8 mSv / year or more including radon (NCRP 1992 and 2009; Moeller 2006). If the projected exposure from licensed activities to the maximally exposed member of the public is already much less than the 10CFR20.1301 limit, and therefore would be less than 5 - 10 % of their annual natural background from the same radionuclides, regulatory requirements to "prove" it is ALARA is not productive and is probably impossible.

Some perspectives on what ALARA is or is not from the HPS and the NCRP may be helpful here:

From Health Physics Society B1013-0, *Background Information on Occupational Radiation Safety Standards and Regulations Are Sound; Position Statement of the Health Physics Society* (Adopted: March 2000, Revised: July 2010)

ALARA is a philosophy of striving for excellence in the practice of health physics. The concept of ALARA has been an important aspect of radiation safety regulations, but has also led to misunderstanding and misuse of the standards. The NCRP has stated "ALARA is simply the continuation of good radiation-protection programs and practices which traditionally have been effective in keeping the average and individual exposures for monitored workers well below the limits" (NCRP 1993). The application of ALARA clearly includes the specification that economic and social factors be considered. Thus, the application of ALARA will inherently be different, i.e., is not able to be standardized across different sources or facilities.

The application of ALARA is founded in the professional judgment of radiation safety managers and personnel and is not, therefore, able to be used as a measure as to whether or not a particular radiation safety program is adequate in comparison with other programs. Additionally, the ALARA concept does not provide a numerical limit below which the ALARA concept is achieved

From NCRP 1999

In its definition of ALARA, the NCRP was very general in stating that, "In many *applications, ALARA is simply the continuation of good radiation-protection programs and practices which traditionally have been effective in keeping the average and individual exposures for*

monitored workers well below the limits" (NCRP, 1993). This was deliberate because sound professional judgment on the part of radiation protection managers in the application of the ALARA principle is an essential aspect of a successful radiation protection program. However, in some instances, the application of the ALARA principle has been inappropriately exaggerated so that the use of radiation has, at times, been unnecessarily restricted and beneficial outcomes forfeited.

The assumption, for radiation protection purposes, that "the risk of stochastic effects is proportional to dose without threshold throughout the range of the dose and dose rates of importance in routine radiation protection" (NCRP, 1993) has led some to the belief that even the lowest exposures are unduly hazardous. The NCRP has always endeavored to ensure that the hazards associated with exposure to ionizing radiation be accurately estimated. It continues to stand by its position stated in 1975 that, "Undue concern, as well as carelessness with regard to radiation hazards, is considered to be detrimental to the public interest" (NCRP, 1975).

Additionally, the specification in the ALARA principle that economic and social factors be considered has at times been overlooked, resulting in excessive monetary costs with little benefit. The ALARA principle should not be misinterpreted as simply a requirement for dose reductions irrespective of the dose level; sound judgment is essential in its proper application

Summary and Implications:

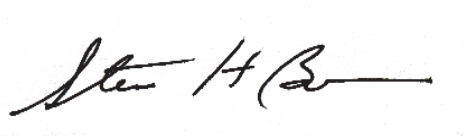
I concur in general with the concerns of the two petitioners that ALARA not be unto itself regulated in the way as it has often been interpreted under 10 CFR 20. My recommendation is as follows:

1. Under circumstances where the licensee has clearly demonstrated and documented that annual exposures are already small relative to the occupational limits of 10 CFR 20.1201 and/or the public exposure limits of 10 CFR 20.1301, there should be no need by the regulator to require "proof" or other wise require the licensee to demonstrate that such exposures are ALARA. It is recognized that some "reasonable judgment" by both licensee and regulator may be involved.

2. However, the routine application of ALARA principles as is defined in 10 CFR 20.1003, including all the various caveats associated with reasonableness, practicality, state of technology and economics, need to be demonstrated as a fundamental component of the facilities radiation protection program and the licensee's systems of dose limitation and control. NRC can evaluate and verify this in accordance with the general requirements for radiation protection programs in 10 CFR 20.1101 (a) and (b). These requirements do not necessarily imply that the licensee must "prove" a specific dose level is ALARA.

Again, thank you for the opportunity to submit these comments and considerations regarding this very important petition for rulemaking.

Steven H. Brown, CHP



REFERENCES

Brenner and Raabe 2001. Brenner D J and Raabe O G. Is the linear no-threshold hypotheses appropriate for use in radiation protection. Radiation Protection Dosimetry. 97, No. 3, pp. 279-285.

Book S A et al 1980. Book S A, Parks NJ, Raabe OG. Bone cancer from radium: canine dose response explains data for mice and humans. Science 208:61– 64.

Evans 1943. Evans RD. Protection of radium dial workers and radiologists from injury by radium. J Industrial Hygiene Toxicol 25:253– 269; 1943.

Evans 1974. Evans RD. Radium in man. Health Phys 27:497–510.

ICRP 1977 International Commission on Radiological Protection. Recommendations of the International Commission on Radiological Protection. ICRP Publication 26. 1977.

ICRP 1983. Cost-Benefit Analysis in the Optimization of Radiation Protection. ICRP Publication 37.

ICRP 2007. International Commission on Radiological Protection. The 2007 recommendations of the International Commission on Radiological Protection. ICRP Publication 103.

Moeller 2006. Moeller D, Sun LSC. *Comparison of natural background dose rates for residents of the Amargosa Valley, NV, to those in Leadville, CO, and the States of Colorado and Nevada.* Health Physics 91:338-353.

NCRP 1992. National Council on Radiation Protection and Measurements. *Exposure of the population in the United States and Canada from natural background radiation*. NCRP Report No. 94.

NCRP 1993. National Council on Radiation Protection and Measurements. Limitations of exposure to ionizing radiation. NCRP Report No. 116.

NCRP 1999. National Council on Radiation Proetction and Measurements.
The application of ALARA for occupational exposures. NCRP Statement No. 8. June.

NCRP 2009. National Council on Radiation Protection and Measurements. Ionizing radiation exposure of the population of the United States. NCRP report No.160.

Raabe O. *Toward Improved Ionizing Radiation Safety Standards*, Health Physics, July 2011, Volume 101, Number 1)

Raabe 2010. Raabe OG. Concerning the health effects of internally deposited radionuclides. Health Phys 98:515–536.

Rosenblatt et al 1990. Rosenblatt L S, Raabe OG, Schlenker RA. Interspecies scaling of risk for radiation-induced bone cancer. Int J Radiat Biol 57:1047–10.